Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Initially, applicants would like to thank Examiner MacFarlane for the courtesy extended to the undersigned representative during the telephone interview conducted on January 19, 2010. The substance of the interview is addressed below.

Claims 1 and 30 have been amended, and claim 26 has been cancelled without prejudice. Claims 1-3, 6, and 29-34 remain pending. No excess claim fees are due with this submission.

Descriptive support for the amendments to claims 1 and 30 is provided in Examples 1 and 2, where daily administration for six, eight, or twelve weeks was shown to be effective. Therefore, no new matter has been introduced by these amendments.

The rejection of claims 1-3, 6, 26, and 29-32 under 35 U.S.C. §112 (first paragraph) for lack of enablement is rendered moot with respect to claim 26 and is otherwise respectfully traversed.

At pages 3-4 of the office action, the PTO asserts that the specification is not enabling with respect to the claimed subject matter. Applicants respectfully disagree.

Applicants have presented data demonstrating the efficacy of three different Growth Hormone Releasing Peptides ("GHRPs"): hexarelin, EP80317, EP80318. The data for hexarelin and EP80317 appear in the Examples and the data for EP80318 are presented with the Declaration of Sylvie Marleau, filed September 8, 2009.

As explained in the specification at pages 8-9 of the application, the invention can be practiced either with GHRPs that induce growth hormone ("GH") secretion or GHRPs that do not induce GH secretion.

Hexarelin is a GHRP that is capable of inducing GH secretion. That is due, at relevant dosages, to the activity of hexarelin on the Ghrelin receptor. (The USPTO at page 4 of the office action mistakenly asserts that hexarelin is a GHRP that does not induce GH release.) However, in the context of the present invention, hexarelin binding to (the hexarelin-binding site on) CD36 is what achieves the reduction in atherosclerotic lesions. Hexarelin was demonstrated to be effective for treating atherosclerosis in Example 1 of the application, producing a 28% reduction in lesion area after 12 weeks of administration. Specifically, the results of Example 1

demonstrate the ability of hexarelin to prevent development of atherosclerosis and to reduce total plasma cholesterol.

EP80317 and EP80318 are GHRPs that do not induce growth hormone secretion. These GHRPs are inactive on the Ghrelin receptor; instead, they bind only to (the hexarelin-binding site on) CD36. EP80317 was shown in Examples 1 and 2 to be effective for inhibiting fatty streak development and reducing lesion area. This was achieved using appropriate dosages for 6, 8, or 12 weeks. EP80318 was shown in the Marleau Declaration to be effective for reducing total aortic lesions, aortic lesion area, and total plasma cholesterol following administration for 6 or 12 weeks.

Thus, applicants have demonstrated that the invention of claim 1 can be practiced without undue experimentation using appropriate dosages of GHRPs that are capable of inducing GH release (hexarelin) and those that do not (EP80317 and EP80318), and that the invention of claim 32 can be practiced without undue experimentation with the latter.

Evidence of statistically insignificant results with hexarelin, relied upon by the PTO at pages 3 and 4 of the office action, are outside the scope of claim 1 because the hexarelin was not administered for a sufficient duration (i.e., six or more weeks). Thus, in consideration of all the evidence of record, there is not a single piece of data indicating that treatment or prevention of atherosclerosis cannot be achieved following administration for six or more weeks with an appropriate dosage of a GHRP. There is no evidence to support the PTO conclusion that undue experimentation would be required.

This same evidence (of insignificant results) with hexarelin also does not support the rejection of claim 32. As noted above, hexarelin is a GHRP that is capable of inducing GH secretion. Thus, the use of hexarelin is outside the scope of claim 32, because hexarelin is not a "GHRP that do[es] not induce secretion of growth hormone." In view of the evidence of record, there is only a single data point among EP80317 and EP80318 that indicates a statistically insignificant result for a GHRP that does not induce secretion of GH release. This is in contrast to the five data points demonstrating the efficacy of the recited class of GHRPs. The mere fact that the claim language encompasses a single ineffective dosage schedule does not negate the evidence of enablement afforded by the record.

For all these reasons, the rejection of claims 1-3, 6, 26, and 29-32 for lack of enablement should be withdrawn.

In view of all of the foregoing, it is submitted that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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